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IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel.

CIVIL ACTION

BRUCE BOISE, et al.

NO. 08-287

v.

110. 00 207

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CEPHALON, INC., et al.

:

O'NEILL, J.

October 9, 2014

MEMORANDUM

Plaintiffs Bruce Boise, Keith Dufour and Andrew Augustine bring this action against defendants Cephalon, Inc. and John Does #1-100 to recover damages and civil penalties on behalf of the United States as qui tam relators pursuant to the False Claims act, 31 U.S.C., §§ 3729 et. seq. (FCA) and analogous state laws. This matter comes before me on Cephalon's motion to dismiss plaintiffs' Fentora claims in their second amended complaint for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1) (Dkt. No. 78) and plaintiffs' response (Dkt. No. 89). Cephalon contends that § 3730(b)(5) of the FCA, known as the "first-to-file" rule, bars (1) the addition of the claims of relators Augustine and Dufour to plaintiffs' second amended complaint with regard to the medications Fentora and Nuvigil; and (2) all of plaintiffs' claims with regard to the medication Provigil. For the reasons that follow, I will partially deny and partially stay Cephalon's motion.

BACKGROUND

In this action, plaintiffs allege that defendants violated the FCA by engaging in the offlabel marketing of various medications, providing kickbacks to physicians prescribing those medications and causing the submission of false claims and false statements to various state and federal programs, amongst other allegations. <u>See generally Dkt. No. 69.</u> On January 3, 2008, Boise filed the original complaint in this action alleging Cephalon's off-label promotion of the medication Fentora. See Dkt. No. 1 at ¶¶ 2, 3. On June 30, 2009, "Doe" commenced a separate action, United States ex rel. Doe v. Cephalon, Inc., No. 09-2926 (E.D. Pa.), by filing a complaint alleging Cephalon's off-label promotion of the medications Fentora and Provigil. See Dkt. 78, Ex. A. On January 14, 2010, in this action, Boise filed his first amended complaint alleging the off-label promotion of Provigil for the first time. See Dkt. No. 14 at ¶¶ 41-64. On Sept. 19, 2013, I dismissed the Doe action without prejudice upon Doe's motion to voluntarily dismiss the complaint. See No. 09-2926, Dkt. No. 44. On February 27, 2014, Boies filed an unopposed motion for leave to file a second amended complaint. See Dkt. No. 66. On February 28, 2014, I granted that motion. See Dkt. No. 67. On March 4, 2014, Boise filed a second amended complaint supplementing his allegations and adding relators Augustine and Dufour. See Dkt. No. 69.

STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of subject matter jurisdiction. A motion under Rule 12(b)(1) may be treated as either a facial attack on the complaint or a factual challenge to the Court's subject matter jurisdiction. Gould Elecs., Inc. v. United States, 220 F.3d 169, 176 (3d Cir. 2000). A court reviewing a facial attack may consider only the allegations of the complaint and any documents referenced therein or attached thereto in the light most favorable to the plaintiff. Id. In reviewing a factual attack, a court may consider evidence outside the pleadings. Id.

A plaintiff bears the burden of persuasion when subject matter jurisdiction is challenged, but the legal standard for surviving a Rule 12(b)(1) motion is a low one. <u>Kehr Packages v.</u>

<u>Fidelcor, Inc.</u>, 926 F.2d 1406, 1409 (3d Cir. 1991). "A claim may be dismissed under Rule

12(b)(1) only if it 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction' or is 'wholly insubstantial and frivolous.'" Gould, 220 F.3d at 178. Nevertheless, "dismissal for lack of jurisdiction is not appropriate merely because the legal theory alleged is probably false, but only because the right claimed is 'so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as not to involve a federal controversy." Kulick v. Pocono Downs Racing Ass'n, 816 F.2d 895, 899 (3d Cir. 1987), quoting Oneida Indian Nation v. Cnty. of Oneida, 414 U.S. 661, 666 (1974).

DISCUSSION

I. Augustine and Dufour's Claims

The FCA's first-to-file rule provides that: "[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). In construing the first-to-file rule, I am "mindful of the need to preserve a balance between the amendment's two competing goals" of providing "adequate incentives for whistle-blowing insiders" and the "discouragement of opportunistic plaintiffs" in qui tam actions. <u>U.S. ex rel. LaCorte v.</u>
SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998).

Cephalon contends that the first-to-file rule not only applies when a party formally intervenes pursuant to Rule 24 of the Federal Rules of Civil Procedure or brings a separate related action but rather "equally applies when additional relators join an existing case." Dkt. No. 78 at 5. Thus, Cephalon argues that Augustine and Dufour's allegations regarding Fentora and Nuvigil are "based on the facts underlying" other pending actions and are barred by the first-to-file rule. In response, plaintiffs contend that as a threshold matter the first-to-file rule does not apply where a relator is joined to an existing action by amended complaint. See Dkt. No. 89 at 5,

12-14. Plaintiffs further contend that even if the first-to-file rule applies in their case, Augustine and Dufour's claims are not "based on facts underlying" pending actions and thus are not barred by the first-to-file rule.

In <u>U.S. ex rel. Precision Co. v. Koch Indus., Inc</u>, the Court of Appeals for the Tenth Circuit held that the addition of new relators by an amended complaint did not trigger the application of the first-to-file rule. 31 F.3d 1015, 1018 (10th Cir. 1994). The Tenth Circuit grounded its holding on its understanding that the meaning of "intervene" in § 3730(b)(5) carries the "plain legal meaning" of intervention under Rule 24. <u>Id.</u> at 1017. The Tenth Circuit reasoned that Congress intended only to ban the addition of relators who were "strangers" to the plaintiff, since a Rule 24 "intervenor need not have a relation to the original plaintiff" to intervene in an action. <u>Id.</u>

Some district courts have adopted <u>Precision's</u> textual analysis of § 3730(b)(5) and limited the first-to-file bar's applicability only to a later separate action or intervention under Rule 24.

<u>See United States v. Educ. Mgmt. Corp.</u>, 871 F. Supp. 2d 433, 459 (W.D. Pa. 2012) (declining to dismiss amendment to add relator since "[t]he plain text of § 3730(b)(5) does not apply to the unique procedural status of this case because [the new relator] is not 'intervening' or bringing a 'related action'"); <u>U.S. ex rel. Howard v. Lockheed Martin Corp.</u>, No. 99-285, 2011 WL 4348104, at *4 (S.D. Ohio Sept. 16, 2011) (following <u>Precision's</u> interpretation).

In contrast, district courts elsewhere have not uniformly followed <u>Precision's</u> analysis. Some courts have simply applied the § 3730(b)(5) bar to consolidated or amended complaints without providing any analysis of the provision's text. <u>See U.S. ex rel. Nowak v. Medtronic, Inc.</u>, 806 F. Supp. 2d 310, 334 (D. Mass. 2011) (applying the first-to-file bar to relators joined through a consolidated complaint); <u>Palladino ex rel. U.S. v. VNA of S. N.J., Inc.</u>, 68 F. Supp. 2d

455, 477 (D.N.J. 1999) (applying the first-to-file bar to a relator added by amended complaint). But see Howard, 2011 WL 4348104, at *4 (following Precision and noting "the Nowak court provided no analysis to explain whether [consolidated] claims were barred as being brought by intervenors or as a related action, and how it reached that conclusion").

Other courts have more directly disputed <u>Precision's</u> interpretation of § 3730(b)(5). In <u>U.S. ex rel. Fry v. Guidant Corp.</u>, the Court applied the first-to-file rule to bar the addition of a second relator to plaintiff's proposed second amended complaint. No. 03-0842, 2006 WL 1102397 (M.D. Tenn. Apr. 25, 2006). The Court concluded that the Tenth Circuit erred in <u>Precision</u> because it carved out an "exception" to the first-to-file rule, reasoning that in contrast the Court of Appeals for the Ninth Circuit and the Court of Appeals for the Fourth Circuit had held that the first-to-file rule was exception-free. <u>See id.</u> at *5-6, <u>citing U.S. ex rel. Lujan v. Hughes Aircraft Co.</u>, 243 F.3d 1181, 1187 (9th Cir. 2001) and <u>U.S. ex rel. LaCorte v. Wagner</u>, 185 F.3d 188, 191 (4th Cir. 1999); <u>see also U.S. ex rel. Manion v. St. Luke's Reg'l Med. Ctr., Ltd.</u>, No. 06-498, 2008 WL 906022, at *7 (D. Idaho Mar. 31, 2008) (applying first-to-file bar to addition of relator by amended complaint because it would "require a departure from Ninth Circuit law" under <u>Lujan</u>).

The Court in <u>Fry</u> also relied upon a policy rationale in rejecting <u>Precision's</u> holding. The Court reasoned that allowing the addition of relators by amended complaint would undermine the first-to-file rule's goal of preventing parasitic claims and duplicative claims that do not help expose fraud or return funds to the federal fisc. <u>See Fry</u>, 2006 WL 1102397, at *6.

But other district courts have concluded upon further inquiry that such policy fears are unfounded. For example, in <u>Howard</u> the Court concluded that "policy considerations favor" the addition of relators by amended complaint, since that mechanism "does not require the

duplicative expenditure of time and resources that a separate action [in another court] would have entailed." 2011 WL 4348104, at *4. Further, the Court reasoned that the addition of relators by amended complaint does not create parasitic claims since relators have "reached a private agreement as to the distribution of any recovery." <u>Id.</u> Finally, the "risk for multiple or inconsistent judgments" that exists in separate actions does not exist where relators are added by amended complaint in a single action. <u>Id.</u>

Like in <u>Howard</u>, here "no party was able to identify binding authority on all fours with the present case." <u>Id.</u> In <u>Education Management</u>, however, the Court reasoned that in <u>SmithKline</u>, the Third Circuit "noted—without disapproval—that in one of the underlying qui tam cases, a relator (Grossenbacher) was 'later joined by' another relator (Robinson)." 871 F. Supp. 2d at 460, <u>citing SmithKline</u>, 149 F.3d at 230. The Court therefore declined to apply the first-to-file bar to a new relator joined by amended complaint. <u>Id.</u>

The plain meaning of § 3730(b)(5), the policy considerations underlying that provision and Third Circuit case law persuade me to conclude that the first-to-file rule does not apply to the voluntary addition of relators by amended complaint in a pending action where relators have entered into a private agreement regarding the division of potential proceeds from the action. I find persuasive the Tenth Circuit's statutory analysis in Precision. First, the meaning of "intervene" in § 3730(b)(5) is unambiguous. I have no reason to doubt that Congress anticipated that the plain meaning of "intervene," when used in the context of a procedural bar to filing FCA actions, would be understood by the courts consistent with the Federal Rules of Civil Procedure.

See Precision, 31 F.3d at 1017 (examining legislative history of § 3730(b)(5)). Second, it is unambiguous that a relator does not bring a later and separate "related action" under § 3730(b)(5) when he or she joins an existing action through an amended complaint. Rather, "all

interested parties can expect to resolve that claim in a single lawsuit" just as intended under § 3730(b)(5). Grynberg v. Koch Gateway Pipeline Co., 390 F.3d 1276, 1279 (10th Cir. 2004).

Contrary to the interpretation of the district courts in Fry and Manion, I find that the Ninth and Fourth Circuits' holdings in Lujan and Wagner do not conflict with the Tenth Circuit's holding in Precision. In Wagner, the Fourth Circuit made the "straight forward" application of § 3730(b)(5) to bar strangers in a separate action from intervening under Rule 24 in an attempt to share in the settlement proceeds of the underlying action. Wagner, 185 F.3d at 190-91. The district court opinion under review in Wagner makes clear that only Rule 24 intervention and not the addition of new relators by amended complaint was at issue in that case. See U.S. ex rel. Lacorte v. Roche Biomedical Labs., Inc., 182 F.R.D. 480, 484 (M.D.N.C. 1998). Similarly, <u>Luian</u> involved the straightforward application of the first-to-file bar to a separate action brought while an earlier FCA action was still pending. Far from the circumstances in this case, where an earlier plaintiff has sought to add additional relators by amended complaint, Lujan arose from an original plaintiff's motion to dismiss a later-filed and separate action pursuant to the first-to-file rule. See Lujan, 243 F.3d at 1186. On those facts the Ninth Circuit concluded that § 3730(b)(5) "unambiguously establishes a first-to-file bar" and rejected the later-filing relator's request for various unrelated exceptions. Lujan, 243 F.3d at 1187.

Policy considerations likewise support reading § 3730(b)(5) to allow the addition of relators by amended complaint. Section 3730(b)(5) was enacted partially to address the concern that as a matter of "fairness claimants alleging the same material facts as prior relators should not share in a *qui tam* award, because their allegations are unlikely to increase the total recovery." SmithKline, 149 F.3d at 234 (3d Cir. 1998). The same fairness concerns are not present where, as here, plaintiffs have consented to join together and share any proceeds of their suit due to the

real or perceived advantage the additional relators bring to the complaint. Thus, such claims are not "parasitic." See Howard, 2011 WL 4348104, at *4. Additionally, § 3730(b)(5) addresses the concern that "duplicative claims do not help reduce fraud or return funds to the federal fisc." because they do not put the government on notice of new fraud. SmithKline, 149 F.3d at 234. While separately filed duplicative actions might not help achieve those goals, a complaint that is potentially strengthened by the addition of new relators with more detailed information might. Indeed, even where the Government declines to intervene in an action initially, the Court can always "permit the Government to intervene at a later date upon a showing of good cause." 31 U.S.C § 3730(c)(3). At the least, allowing the second amended complaint to proceed in this case would not create any of the clear problems of efficiency and conflicting judgments like later, separately filed and related actions. See Howard, 2011 WL 4348104, at *4. Lastly, I am persuaded that dismissal is not warranted on the basis of the first-to-file bar because the Court of Appeals has noted without disapproval the joining of an additional relator to an existing FCA action. See SmithKline, 149 F.3d at 230.

For the foregoing reasons, I will deny defendant's motion to dismiss Augustine and Dufour's claims from plaintiffs' second amended complaint.

II. Plaintiffs' Provigil Claims

Cephalon's motion to dismiss also contends that plaintiffs' Provigil allegations are barred by the first-to-file rule because those claims were first filed in plaintiffs' first amended complaint when the <u>Doe</u> action, which also alleged that Cephalon violated the FCA with regard to Provigil, was still pending. <u>See</u> Dkt. No. 78 at 6-9. Plaintiffs respond by arguing that the timing of the filing of their second amended complaint controls the first-to-file inquiry. Thus, plaintiffs assert that the <u>Doe</u> action was not pending when their Provigil claims were filed because I dismissed

the <u>Doe</u> action without prejudice on September 19, 2013 and plaintiffs filed their second amended complaint in this action on February 4, 2014. Plaintiffs contend that the <u>Doe</u> action cannot be considered a "pending action" under 3730(b)(5) after its dismissal and therefore their Provigil claims are not barred.

The critical underlying issue is the meaning of "pending" under § 3730(b)(5). By its terms, the first-to-file rule applies where there is an underlying "pending action." 31 U.S.C. § 3730(b)(5). Thus, some Courts of Appeals have held that a later-filed action may continue or be refiled after an earlier-filed related action is dismissed. See U.S. ex rel. Chovanec v. Apria Healthcare Grp. Inc., 606 F.3d 361, 365 (7th Cir. 2010); In re Natural Gas Royalties Qui Tam Litig., 566 F.3d 956, 964 (10th Cir. 2009); U.S. ex rel. Carter v. Halliburton Co., 710 F.3d 171, 183 (4th Cir. 2013), cert. granted, 134 S. Ct. 2899 (2014).

But other Courts of Appeals have read the phrase "pending action" as a shorthand reference for the earlier action rather than a temporal limitation on § 3730(b)(5)'s application. See U.S., ex rel. Shea v. Cellco P'ship, 748 F.3d 338, 343 (D.C. Cir. 2014) (finding that "[t]he simplest reading of "pending" is the referential one; it serves to identify which action bars the other"); U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P., 579 F.3d 13, 32 (1st Cir. 2009) (applying first-to-file bar where earlier-filed action was dismissed before filing of later related action). The issue then is not merely the timing of the filing of the later action, but whether an earlier filed action that is dismissed bars *all* later related actions under § 3730(b)(5).

On July 1, 2014 the Supreme Court granted certiorari in <u>U.S. ex rel. Carter v. Halliburton</u>

<u>Co.</u> on the question of whether § 3730(b)(5) bars later related actions once an earlier-filed action has been dismissed. 710 F.3d 171 (4th Cir. 2013), <u>cert. granted</u>, 134 S. Ct. 2899 (2014). Thus, I

will stay consideration of Cephalon's motion to dismiss plaintiffs' Provigil claims pending the Supreme Court's resolution of this question.

CONCLUSION

For the reasons set forth above, I will deny Cephalon's motion to dismiss with regard to Augustine and Dufour's Fentora and Nuvigil claims and will stay consideration of Cephalon's motion to dismiss with regard to plaintiffs' Provigil claims.

An appropriate Order follows.

10/9/14 males